

REMARKS

New claims 11 - 31 are presented to provoke an interference with U.S. patent No. 6,192,891, a copy of which is Attachment A hereto. As discussed below, the applicants propose new claim 11, which is identical to claim 21 of the '891 patent, as an interference Count. Claim 31 is presented as an alternate Count.

New Independent Claim 11

New claim 11 is identical to claim 21 of the '891 patent. It is supported in the specification as follows:

11. A diagnostic and medication delivery system, said system comprising:

a housing;

a monitor integrally disposed in the housing for monitoring a characteristic of a sample of a bodily fluid;

a medication delivery pen removably mounted in said housing; and

a lancer removably mounted in said housing, wherein said monitor is not integrally attached to said medication delivery pen,

such that a user is provided with the flexibility to use different medication delivery pens with said system but only one monitor.

BGM 30 provides diagnostics; doser 20 provides medication delivery

cap 10

Page 6, lines 21-22: "one embodiment of the invention might be a cap where the BGM 30 is an integral part."

Doser 20 is inserted into the sleeve of the cap 10.

Page 7, lines 29-30 "lancet device 40 [is] removably attached to the BGM by the locking means 31." Fig. 3 shows that "locking means 31" is a pair of hooks, i.e., that are received in the "housing"

Page 10, lines 32-33: "So with this set of modules an optimal compact set can be customised with the things needed for a given situation."

The applicants notes that, while claim 11 (and corresponding claim 21 of the '891 patent) recite a lancer removably mounted "in" said housing, the drawings of the '891 patent show that, in the '891 patent, only a small part of the lancer 108 is actually disposed "in" the housing 102. Thus, in order for claim 21 of the '891 patent to be supported by its own specification, the term "in" must be construed broadly to mean that only a small part of the lancer must be disposed "in" the housing.

In the present application, as shown in Fig. 3, when the device is assembled, the lancet device 40 lies flush against the cap 10, and therefore the hooks 31 of the lancet device 40 must inherently be disposed "in" the cap (which, in the embodiment disclosed on page 6, lines 22, forms the housing for the BGM 30). Thus, if claim 21 of the '891 patent is supported by the '891 specification, claim 11 is supported by the present specification.

Claim 12

Dependent claim 12, which corresponds to claim 22 of the '891 patent and recites that "the monitor is integrated into the housing so that the housing and monitor form a single operable unit," is supported in the present specification at page 6, line 22.

Claim 13

Claim 13 corresponds to claim 23 of the '891 patent, and states that "the monitor is removably mounted to said housing." Claim 13 is inconsistent with its parent claim, which recites that the monitor and housing are "integral." Moreover,

the '891 patent discloses no embodiment where "the monitor is removably mounted to the housing." Nevertheless, the present specification discloses embodiments where the monitor is removably mounted to the housing, e.g., in Fig. 3.

Claim 14

Claim 14, which corresponds to claim 24 of the '891 patent, recites that the "housing has a first compartment adapted to receive and store the medication delivery pen and a second compartment adapted to receive and store the lancer." In the present application, the sleeve constitutes a first compartment for receiving the doser 20. As noted above, while not shown, the cap 10 of the present invention inherently has openings to receive the hook members 31.

Claim 15

Claim 15, which corresponds to claim 25 of the '891 patent, recites that "said first and second compartments are integrally formed with and embedded in said housing." As shown in Fig. 2, for example, of the '891 patent, the "first compartment" is merely a sleeve, similar to the sleeve in the cap 10 of the present application. Thus, if claim 15 is supported by the '891 patent, the term "embedded in" must be construed broadly. As noted above, in the present invention the doser 20 is received in a sleeve in the housing, similar to the '891 patent, and the hook elements 31 are received in openings (compartments) "formed with" the cap 10.

Claim 16

Claim 16, which corresponds to claim 26 of the '891 patent, recites that "said monitor includes a test strip interface for receiving a test strip on which the fluid sample is located." The present specification discloses that the BGM 30 includes a test strip interface 34 for receiving an analyzing test strips. Page 7, lines 1-4.

Claims 17-18

Claims 17-18, which correspond to claims 29-30 of the '891 patent, recite that "the medication delivery pen is an electronic pen." As disclosed on page 10, line 15, the doser 20 of the present application may constitute "an insulin injecting pen." As shown in the drawings and described in the specification, the doser 20 of Figure 6 contains an electronic display 84.

Claim 19

Claim 19, which corresponds to claim 33 of the '891 patent, recites that the "monitor includes a display for displaying blood glucose levels." This feature is expressly disclosed in the present application at page 7, lines 1-4.

Claim 20

Claim 20, which corresponds to claim 35 of the '891 patent, recites that the "housing further includes a third compartment adapted to store ancillary items including test strips." Claim 20 does not require that such "third compartment" be separated from the first or second compartment (indeed, claim 8 envisions that

compartments can include sub-compartments). Figs. 6 and 8 of the present application disclose embodiments where compartments exist for both a doser 80 and a storage compartment 70.

Claim 21-24

Claim 21, which corresponds to claim 36 of the '891 patent, recites that the "third compartment includes a cover for securing the ancillary items therein." As shown in Figs. 6 and 8, when the drawer 70 slides into the cap 10, the sleeve in the cap (i.e., the third compartment in the housing) forms a cover for securing any ancillary items which are present in the drawer 70.

Claim 22, which corresponds to claim 37, recites that the "housing has first and second opposing ends and said first and second compartments are located proximate to different ones of the first and second ends." "Proximate," of course, is a relative term. As shown in Fig. 3, for example, of the present drawings, the opening for the "first compartment" (i.e., the sleeve for receiving the doser) is disposed at one end of the housing. Although the locations of the openings in the cap 10 that receive the hooks 31 of the lancer device 40 (i.e., in the embodiment where the BGM and cap 10 are integral) are not expressly shown, based on the location of the hooks 31 shown in the drawings it is evident that the distal opening would be "proximate" to the opposite end of the cap 10.

Claim 23, which corresponds to claim 44 of the '891 patent, recites that "the medication delivery pen is a mechanical pen." As disclosed on page 5, line

34- page 6, line 2, "[t]he doser 20 comprises a turning wheel 21 for adjusting, either electronically or manually, the level/amount of medication to be administered . . . "

An embodiment of a mechanical dose-setting and injection pen mechanism is disclosed in connection with Figure 6. Thus, as disclosed on page 10, the doser 80 includes "a turning wheel 85 for adjusting the level/amount of medication to be administered. . . . After the appropriate level of medication has been set, the user can press the release button 82, which manually injects/administers the selected amount of medication through the needle." Lines 14-22.

Claims 24-30

Independent claim 24 (which is identical to claim 1 of the '891 patent) is substantially the same as new claim 11 and is supported in the present specification as set forth in connection with claim 11.

Dependent claim 25 (which is identical to claim 2 of the '891 patent) does not appear to add any limitation to claim 24, but is expressly supported in the present specification at page 6, line 22. Claim 26 (which is identical to claim 3 of the '891 patent) corresponds to new claim 16 and is supported in the specification for the same reasons as claim 16. Claims 27-29 (which are identical to claims 8-10 of the '891 patent) correspond to new claims 20-21 and are supported for the same reasons. And, claim 30 (which is identical to claim 12 of the '891 patent) corresponds to claim 22 and is supported for the same reason as claim 22.

Claim 31

Claim 31 is identical to new claim 11 except that, whereas claim 11 recites that lacer is removably "mounted in" said housing, claim 31 recites that the lacer is removably "secured to" said housing (which function is performed by the elements 31).

The Non-Copied Claims Are Obvious Over The Parent Claims

The foregoing amendments copy all of the claims of the '891 patent except for claims 4-7, 11, and 13-20, which depend on independent claim 1, and claims 27-28, 31-32, 34, 38-43, and 45, which depend on independent claim 21. As discussed below, such dependent claims do not appear to recite any limitations which would render such dependent claims independently patentable over the parent claim.

Claims 4 and 27 of the '891 patent recite that the device includes "at least one data port disposed on the housing for transferring information to and receiving information from an external device." Claims 5 and 28 recite that "said data port is coupled to the monitor for receiving and downloading the monitored characteristics of the fluid." And, claim 6 recites that "said data port additionally receives and downloads information from an electronic medication delivery pen disposed in the first compartment." While the present application does not expressly disclose a data port, the use of a data port to upload or download data from a monitor and pen is well known. See, Castellano U.S. patent No. 5,536,249, e.g., Fig. 4 (a copy of which is attached as Attachment B).

Claim 31, which is dependent on claim 28, recites that the delivery pen is electronic. The pen disclosed in the present application is electronic. Claim 32, which is dependent on claim 31, recites that the data port additionally receives and downloads information from the pen. As shown in Fig. 4 of Castellano '249, the data port communicates electronically with the pen.

Claims 7 and 34, which are dependent on claims 1 and 33, further recite that the blood glucose display is "located on an inner surface of the second compartment that is exposed when the lancet is not disposed therein." While this feature is not disclosed in the present application, the choice of location of the monitor on the housing is a matter of design choice and not separately patentable.

Claim 11 recites that the third compartment is "partitioned into at least two sub-compartments." While the present specification does not disclose a third compartment which is sub-divided, it does disclose the concept of subdividing compartments in Figs. 6 and 8, and thus this feature cannot be independently patentable.

Claims 13 and 38, which depend on claims 12 and 37, recite that "the monitor includes a test strip interface for receiving a test strip on which the fluid sample is located, and wherein said test strip interface is located on the end of the housing proximate to the second compartment." While the present application discloses orienting the BGM so that the test strip opening 34 is located near the first compartment, there is nothing inherently patentable about reversing the orientation.

Claim 39, which depends on claim 24, recites that "at least a display of the monitor is located within the second compartment." The location of the second compartment is a matter of design choice and does not recite a separate basis for patentability.

Claims 15 and 40, which are dependent on claims 12 and 39, recite that "the monitor includes a test strip interface for receiving a test strip on which the fluid sample is located, and wherein said test strip interface is also located in the second compartment." The former limitation is disclosed in the present application (as well as other prior art). There does not appear to be any support for the latter limitation in the '891 drawings (See, 37 C.F.R. § 1.83(a): "The drawing in a non-provisional application must show every feature of the invention specified in the claims"), insofar as the test strip openings 122 are consistently shown as being located on one of the ends (Figs. 3 and 7) or sides (Figs. 4-5) of the housing, and not in the second compartment. Nevertheless, the location of the test strip opening is a matter of design choice.

Claim 16, which depends on claim 1, recites that the device is "further comprising a lancer integrally formed with the second compartment so that the housing, the monitor, and the lancer form a single operable unit." It is not clear whether the "lancer" referred to in claim 1 is the same as, or different from, the lancer already defined in claim 1. Assuming the latter, claim 16 is inconsistent with claim 1, which recites that the lancer and housing are separate units, not integral with one

another. Claim 16 is thus not valid. Assuming the former (i.e., that the claim 16 lancer is a second lancer), the '891 patent lacks any enabling disclosure, and the claim is still invalid.

Claims 17 and 18 recite the device of claim 1 and 16, respectively, "further comprising a medication delivery pen integrally formed with the first compartment so that the housing, the monitor, and the medication delivery pen form a single operable unit." Again, it is unclear whether the pen recited in claims 17 and 18 is the same as, or different from, the pen recited in parent claims 1 and 16. However, as in the case of claim 16, either claim 17 is inconsistent with claim 1 (if it is the same pen) or lacks support in the specification (if it refers to a different pen), and is invalid.

Claims 19, 20, and 41, which depend on claims 2, 7, and 24, respectively, further recite that "the first and second compartments include portions that extend internal to the housing for receiving and protecting a needle of the medication delivery pen needle and a lancet of the lancer, respectively." Fig. 3 of the present application discloses the features of the parent claims (2, 7, and 24) on which claims 2, 7, and 41 depend, together with a first compartment that extends internal to the housing for receiving and protecting a needle of the doser 20. The second compartment in Fig. 3 does not include a portion for protecting the lancer of a lancet device. However, given the disclosure of the present invention of using a receiving sleeve to protect the sharp needle 27 of the doser 20, combined with the disclosure of the '891

patent that conventional lancet devices also include a sharp, projecting part, i.e., a lancer, that needs to be covered between uses, Col. 3, lines 48-50, it would have been obvious, if desired, to provide a second sleeve to receive the lancet device. Alternatively, it would have been obvious to use the sleeve of the cap 10 to receive both the doser 20 and the lancet device 40, in a manner similar to Figs. 6, 8, or 9.

Claims 42 and 43, which depend on claims 22 and 33, respectively, recite that "the medication delivery pen and the monitor are in electrical communication with one another." Such feature, while not disclosed in the present application, is well known, e.g., as disclosed in the Castellano '249 patent.

Finally, claims 14 and 45, which depends on claim 43, recites that the monitor includes a display and operates based on user input in two operating modes. In a first mode, operable when the pen is stored in the compartment, the monitor displays blood glucose level responsive to user input. In the second mode, operable when the pen is removed from the compartment, the monitor, responsive to user inputs, displays insulin dosage levels. As disclosed in the specification, due to the fact that, in the second mode, the pen has been removed (i.e., and thus cannot communicate with the monitor), dose amounts administered must be entered manually by the user. Col. 4, line 58-60.

The present specification discloses a monitor which calculates and displays blood glucose levels responsive to user inputs, which can operate when the doser 20 is docked in the sleeve of the cap 10. Page 7, lines 1-4 . While the present

application does not disclose providing inputs to the monitor to record injected doses, providing such input information to a monitor is disclosed in the Castellano '249 patent. See. col. 13, lines 39-44 and col. 15, line 64 - col. 16, line 2

Proposed Interference Count

The present application is a divisional of U.S. patent application No. 09/312,796, filed on May 17, 1999, and claims priority on U.S. provisional application No. 60/087,187, filed on May 29, 1998. The application claims foreign priority on Danish application No. PA 1998 00714, filed on May 20, 1998. The '891 patent was filed on April 26, 1999.

The '891 patent, a copy of which is attached, contains two independent claims, claims 1 and 21. For the reasons discussed above, the applicants believe that all of the claims of the '891 patent are obvious over claim 21, and therefore claim 21 would constitute a suitable count for an interference.

As discussed above, the applicants believe that '891 claim 21 is fully disclosed in the present application. The applicants have therefore copied '891 claim 21 as new claim 11 in the present application, as the proposed Count for an interference between the present application and the '891 patent.

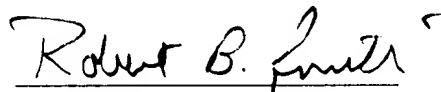
As an alternative, if the Examiner determines that new claim 11 is not fully supported by the specification, the applicants have presented new independent claim 31 as an alternative Count.

Finally, while the applicants believe that all of the claims of the '891 patent would be obvious over new claims 11 or 31 of the present application, and that a single interference count is sufficient, in the event that the Examiner believes that multiple Counts are needed, the applicants have copied additional claims from the '891 patent which are fully disclosed in the present application, as discussed above

CONCLUSION

For the reasons discussed above, the applicants respectfully request that the Examiner declare an interference between the present application and U.S. patent No. 6,192,891. The applicants suggest that new claim 11 form the basis of a single interference count.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Robert B. Smith", with a horizontal line underneath it.

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